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EXAMINER
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COTTON, ABIGAIL MANDA

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,407	<b>Applicant(s)</b> FRANCHI ET AL.	
	<b>Examiner</b> Abigail M. Cotton	<b>Art Unit</b> 1617	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/1/04, 3/22/05 and 11/18/05.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-84 is/are pending in the application.
- 4a) Of the above claim(s) 36-39, 45-66, 70-73 and 80-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-35, 40-44, 67-69, 74-79 and 84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date: _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/1/2004</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 31-84 are pending in the application as of the response received on November 18, 2005. Of these, claims 36-39, 45-66, 70-73 and 80-83 are withdrawn as being drawn to a non-elected invention.

### ***Election/Restrictions***

Applicant's election with traverse of the claims of Group I in the reply filed on November 18, 2005 is acknowledged. The traversal is on the ground(s) that no lack of unity was found during the prosecution of the PCT application, and because Applicant's assert that the search for both groups would not pose an undue burden on the office.

This is not found persuasive because according to 37 CFR 1.475 (a), an international or national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Furthermore, according to 37 CFR 1.475(c), if an application contains claims to more or less than one of the combinations of categories set forth in paragraph (b) of this section, unity of invention might not be present. Also, according to 37 CFR 1.475(d), if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims. See PCT Article 17(3)(a) and § 1.476(c).

Accordingly, the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature because: the invention of Group I is drawn to a composition and method for slimming and reducing subcutaneous fat with phytosphingosine, while the invention of Group II is drawn to a method of stimulating synthesis of leptin by adipocytes with a composition comprising phytosphingosine.

Therefore, claims 31-48 and 67-84, drawn to a method and composition for slimming the human body and reducing subcutaneous fat with a composition comprising phytosphingosine or one of its cosmetically acceptable salts, are considered the main invention (Group I.) Claim(s) 49-66, drawn to a method for stimulating synthesis of leptin by adipocytes with a composition comprising phytosphingosine or one of its cosmetically acceptable salts, are considered the second invention (Group II.) As each method of use of the composition relates to a separate field of medical technology, a single general inventive concept is not seen to be present.

Furthermore, the search for Groups I and II is believed to pose an undue burden on the Office because, even though a search for the subject matter of Groups I and II may be overlapping, the searches would not be co-extensive. The search for Group I has required a focus on a composition and method for slimming and reducing subcutaneous fat, whereas a search for Group II would require a focus on the stimulating of the synthesis of leptin by adipocytes.

The requirement is still deemed proper and is therefore made FINAL. Claims 49-66 are withdrawn as drawn to a non-elected group of invention.

Applicant's election without traverse of the species of lipolytic agent comprising adenylate cyclase enzyme activating agents in the reply filed on November 18, 2005, is acknowledged. Accordingly, this species restriction requirement is deemed proper and

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is therefore made FINAL. Claims 36-39, 45-48, 70-73 and 80-83 are withdrawn as being drawn to non-elected species of the invention.

### ***Priority***

Applicant's claim of foreign priority to FRANCE 0202675 filed March 1, 2002, is acknowledged.

### ***Claim Objections***

Claim 44 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In particular, claim 41, from which claim 44 depends, recites that the adenylate cyclase enzyme activating agent is selected from the group consisting of forskolin and plant extracts containing the same, whereas claim 44 specifies that the adenylate cyclase activating agent is an extract of the plant *Tephrosia purpurea*, which is not disclosed as being a plant extract having forskolin, as required by claim 41. Accordingly, claim 44 does not further limit the claim from which it depends. Appropriate correction is required. The Examiner respectfully suggests that the dependency may be corrected by amending claim 44 to depend from claim 40.

In the interests of compact prosecution and for the purposes of applying prior art, claim 44 is being interpreted as depending from claim 40.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-32, 34 and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996.

Jackson et al. teaches a composition for topical application to the skin comprising from 0.0001 to 10% by weight of one or more ceramide pathway intermediates (see abstract, in particular.) Jackson et al. teaches that the composition can be applied to human skin for the eradication or reversal of skin aging, removal of rough or dry skin and improving the loss of elasticity and flexibility of skin, among others (see column 2, lines 50-60, in particular.) Jackson teaches that a preferred ceramide pathway intermediate is phytosphingosine (see column 4, lines 14-20, in particular.)

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Accordingly, Jackson et al. teaches a method of cosmetic treatment comprising the application of phytosphingosine to parts of the body, as recited in claim 31. The human skin as taught by Jackson et al. is considered to be a part of the body in need of a slimming effect.

It is noted that claim 31 is directed to a method that obtains a slimming effect on parts of the body in need thereof by applying the phytosphingosine. However, the teachings of Jackson et al. anticipate the claimed composition, the property of such a claimed composition is also taught by the prior art, since the properties, namely the slimming effect, are inseparable from its composition. Therefore, if the prior art teaches the cosmetic composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product. Accordingly, Jackson et al. anticipates the method of claim 31.

It is furthermore noted that claim 32 is directed to a method that is intended for reducing subcutaneous excess fat by applying the phytosphingosine. However, the teachings of Jackson et al. anticipate the claimed composition, the property of such a claimed composition is also taught by the prior art, since the properties, namely the slimming effect, are inseparable from its composition. Therefore, if the prior art teaches the cosmetic composition, then the properties are also taught by the prior art. In re



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Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01.

The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

Regarding claim 34, Jackson et al. exemplifies a cosmetic composition comprising 0.1% phytosphingosine (see Example 1, in particular), and thus teaches providing the weight percentage recited in the claim.

Regarding claim 84, it is noted that the claim recites that the active agent is present in the composition in an effective amount for stimulating the synthesis of leptin by adipocytes. It is furthermore noted that Jackson et al. exemplifies providing 0.1% of phytosphingosine. Thus, as the teachings of Jackson et al. anticipate the claimed composition, the property of such a claimed composition is also taught by the prior art, since the properties, namely stimulating the synthesis of leptin by adipocytes, are inseparable from its composition. Therefore, if the prior art teaches the cosmetic composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

Claims 31-34 and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/53568 to Streekstra et al, published September 14, 2000.

Streekstra et al. teaches sphingoid base derivatives for topical use (see abstract, in particular.) Streekstra et al. teaches that the composition are potent effectors of skin cell differentiation and proliferation, and are used in cosmetic composition for the treatment of skin disorders such as dry skin (see page 1, lines 10-30, in particular.) Streekstra exemplifies providing phytosphingosine hydrochloride (see Example 3, in particular)

Accordingly, Streekstra et al. teaches a method of cosmetic treatment comprising the application of phytosphingosine to parts of the body, as recited in claim 31. The skin as taught by Streekstra et al. is considered to be a part of the body in need of a slimming effect.

It is noted that claim 31 is directed to a method that obtains a slimming effect on parts of the body in need thereof by applying the phytosphingosine. However, the teachings of Streekstra et al. anticipate the claimed composition, the property of such a claimed composition is also taught by the prior art, since the properties, namely the slimming effect, are inseparable from its composition. Therefore, if the prior art teaches the cosmetic composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess

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the same properties as the instantly claimed product. Accordingly, Streekstra et al. anticipates the method of claim 31.

It is furthermore noted that claim 32 is directed to a method that is intended for reducing subcutaneous excess fat by applying the phytosphingosine. However, the teachings of Streekstra et al. anticipate the claimed composition, the property of such a claimed composition is also taught by the prior art, since the properties, namely the slimming effect, are inseparable from its composition. Therefore, if the prior art teaches the cosmetic composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

Regarding claim 33, Streekstra et al. teaches providing phytosphingosine hydrochloride (see Example 3, in particular.) Regarding claim 34, Streekstra et al. teaches that the sphingoid bases can be provided in an amount of from 0.02 to 1 wt% (see page 4, lines 5-10, in particular), which meets the limitation of the claims.

Regarding claim 84, it is noted that the claim recites that the active agent is present in the composition in an effective amount for stimulating the synthesis of leptin by adipocytes. It is furthermore noted that Streekstra et al. exemplifies providing 0.02 to 1% of phytosphingosine. Thus, as the teachings of Streekstra et al. anticipate the

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claimed composition, the property of such a claimed composition is also taught by the prior art, since the properties, namely stimulating the synthesis of leptin by adipocytes, are inseparable from its composition. Therefore, if the prior art teaches the cosmetic composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31-32, 34 and 84 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,372,236 to Park et al. issued April 16, 2002.

Park et al. teaches compositions for skin care and their medicinal uses, which includes phytosphingosine (see abstract, in particular.) Park et al. teaches that the composition inhibits the growth of skin microorganisms and improves the wrinkle condition of skin, and treats inflammation of the skin (see abstract, in particular.)

Accordingly, Park et al. teaches a method of cosmetic treatment comprising the application of phytosphingosine to parts of the body, namely skin, as recited in claim 31. The skin as taught by Park et al. is considered to be a part of the body in need of a slimming effect.

It is noted that claim 31 is directed to a method that obtains a slimming effect on parts of the body in need thereof by applying the phytosphingosine. However, as the teachings of Park et al. anticipate the claimed composition, the property of such a claimed composition is also taught by the prior art, since the properties, namely the slimming effect, are inseparable from its composition. Therefore, if the prior art teaches the cosmetic composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product. Accordingly, Park et al. anticipates the method of claim 31.

It is furthermore noted that claim 32 is directed to a method that is intended for reducing subcutaneous excess fat by applying the phytosphingosine. However, as the teachings of Park et al. anticipate the claimed composition, the property of such a claimed composition is also taught by the prior art, since the properties, namely the slimming effect, are inseparable from its composition. Therefore, if the prior art teaches

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the cosmetic composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

Regarding claim 34, Park et al. teaches that the phytosphingosine can be provided in an amount as low as 1 wt% (see column 4, lines 43-50, in particular), which meets the limitation of the claims.

Regarding claim 84, it is noted that the claim recites that the active agent is present in the composition in an effective amount for stimulating the synthesis of leptin by adipocytes. It is furthermore noted that Park et al. teaches providing as low as 1% of phytosphingosine. Thus, as the teachings of Park et al. anticipate the claimed composition, the property of such a claimed composition is also taught by the prior art, since the properties, namely stimulating the synthesis of leptin by adipocytes, are inseparable from its composition. Therefore, if the prior art teaches the cosmetic composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996, as applied to claims 31-32, 34 and 84 above, and further in view of WO 00/53568 to Streekstra et al, published September 14, 2000.

Jackson et al. is applied as discussed for claims 31-32 and 84 above, and teaches applying a composition to skin comprising a ceramide pathway intermediate, such as phytosphingosine. Jackson et al. furthermore teaches that the composition can be provided with water as a vehicle (see column 6, lines 15-20, in particular.)

Jackson et al. does not specifically teach providing phytosphingosine in the form of phytosphingosine hydrochloride, as recited in claim 33.

Streekstra et al. teaches that forming the salt of sphingoid bases, such as the hydrochloric acid salt phytosphingosine, provides a sphingoid compound having better

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solubility in topical formulations containing water than their free base counterparts (see page 2, lines 1-35, and page 3, lines 15-17, and Example 3, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the phytosphingosine hydrochloride of Streekstra et al. in the phytosphingosine-containing composition of Jackson et al, with the expectation of providing a phytosphingosine form having improved solubility in the water-containing vehicle of Jackson et al.

Claims 35, 40-42, 67, 69 and 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996, as applied to claims 31-32, 34 and 84 above, and further in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997.

Jackson et al. is applied as discussed for claims 31-32, 34 and 84 above, and teaches a method of applying a composition comprising a ceramide pathway intermediate such as phytosphingosine to the skin. Jackson et al. further teaches that the composition can be used in the treatment of skin to reduce or delay the development of wrinkles associated with advancing age or with sun-induced aging (see column 2, lines 10-20, in particular.) Jackson et al. also teaches that further cosmetic adjuncts can be provided in the composition (see column 11, line 30 through column 1, line 15, in particular.)



Jackson et al. does not specifically teach providing a composition with a lipolytic agent as recited in claims 35, 40-44, 67-69 and 74-79.

Bombardelli et al. teaches a composition comprising esculoside in combination with an adenylate cyclase stimulator (lipolytic agent) in topical formulations (see abstract, in particular.) Bombardelli et al. teaches that the ingredient can act to improve skin early aging, particularly face and neck skin (see column 3, lines 1-12, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the ingredients including the adenylate cyclase stimulator of Bombardelli et al. in the composition of Jackson et al, because Jackson et al. teaches applying a composition to reduce wrinkles associated with skin aging, and teaches the composition can have other adjuvants, and Bombardelli et al. teaches that ingredients including an adenylate cyclase stimulator act to improve skin aging. Thus, one of ordinary skill in the art would have been motivated to provide an adjuvant comprising the adenylate cyclase stimulator-containing ingredients of Bombardelli et al. in the wrinkle-treating composition of Jackson et al. and applying to skin, with the expectation of providing a composition that treats signs of the early aging of skin such as skin wrinkles. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea

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of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Accordingly, the method of claim 35 is obvious over Jackson et al. and Bombardelli et al.

Regarding the composition of claim 67, it is noted that Jackson et al. teaches a composition for reducing wrinkles associated with ageing, whereas Bombardelli et al. teaches that a composition with ingredients including an adenylate cyclase enzyme stimulator (activating agent) can improve the early aging of skin, as discussed for claim 35. Jackson et al. also teaches that the composition can comprise a cosmetically acceptable vehicle (see column 5, lines 60-68, in particular), as recited in the claim. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the adenylate cyclase stimulator-containing ingredients of Bombardelli et al. in the wrinkle-treating composition of Jackson et al., with the expectation of providing a composition that treats signs of the early aging of skin such as skin wrinkles. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.) Accordingly, the composition of claim 67 is also obvious over Jackson et al. and Bombardelli et al.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.) Thus the intended use recited in claim 67, namely that the cosmetic composition is “notably intended for reducing subcutaneous excess fat,” is not afforded patentable weight.

Regarding claims 40 and 74, Bombardelli et al. teaches providing an adenylate cyclase stimulator (activating agent), as discussed for claims 35 and 67 above. Regarding claims 41 and 75, Bombardelli et al. teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.) Regarding claims 42 and 76, Bombardelli et al. teaches that the adenylate cyclase stimulator can comprise from about 0.1 to 1% of the composition (see column 1, lines 40-65, in particular), and thus teaches an amount that meets the limitations of the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of adenylate cyclase stimulator provided in the composition, according to the guidance provided by Bombardelli et al. to provide a composition having desired sin treatment effects. It is

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noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 69, Jackson et al. teaches a cosmetic composition comprising 0.1% phytosphingosine (see Example 1, in particular), and thus teaches providing the weight percentage recited in the claim.

Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996 in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, as applied to claims 35, 40-42, 67, 69 and 74-76 above, and further in view of WO 00/53568 to Streekstra et al, published September 14, 2000.

Jackson et al. and Bombardelli et al. are applied as discussed for claims 35, 40-42, 67, 69 and 74-76 above, and teach a composition for skin comprising a ceramide pathway intermediate, such as phytosphingosine, and an adenylate cyclase inhibitor. Jackson et al. furthermore teaches that the composition can be provided with water as a vehicle (see column 6, lines 15-20, in particular.)

Jackson et al. and Bombardelli et al. do not specifically teach providing phytosphingosine in the form of phytosphingosine hydrochloride, as recited in claim 68.

Streekstra et al. teaches that forming the salt of sphingoid bases, such as the hydrochloric acid salt phytosphingosine, provides a sphingoid compound having better solubility in topical formulations containing water than their free base counterparts (see page 2, lines 1-35, and page 3, lines 15-17, and Example 3, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the phytosphingosine hydrochloride of Streekstra et al. in the phytosphingosine-containing composition of Jackson et al. and Bombardelli et al, with the expectation of providing a phytosphingosine form having improved solubility in the water-containing vehicle of Jackson et al and Bombardelli et al.

Claims 43 and 74 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996 in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, as applied to claims 35, 40-42, 67, 69 and 74-76 above, and further in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.

Jackson et al. and Bombardelli et al. are applied as discussed for claims 35, 40-42, 67, 69 and 74-76 above, and teach a composition comprising phytosphingosine and an adenylate cyclase stimulator, and a method for applying the composition to the skin.

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Bombardelli et al. furthermore teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.)

Jackson et al. and Bombardelli et al. do not specifically teach providing an adenylate cyclase stimulator that is an extract of *Coleus forskohlii* or *Plectranthus barbatus*, as recited in claims 43 and 74.

Andre et al. teaches that an extract of *Coleus forskohlii* contains forskoline (forskolin) and is known for its activity in stimulating adenylate cyclase (see column 5, lines 60-68, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was known would have found it obvious to provide the *Coleus forskohlii* extract of Andre et al. in the phytosphingosine and adenylate cyclase stimulator composition and method of Jackson et al. and Bombardelli et al, because Jackson et al. and Bombardelli et al. teach that an adenylate cyclase stimulator such as forskolin can be provided, and Andre et al. teaches that an extract of *Coleus forskohlii* provides the forskolin adenylate cyclase stimulator. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extract of Andre et al. in the composition and/or method of Jackson et al. and Bombardelli et al, with the expectation of providing a suitable forskolin containing adenylate cyclase stimulator in the composition.

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Accordingly, claims 43 and 74 are obvious over the teachings of Jackson et al, Bombardelli et al. and Andre et al.

Claims 35, 40, 44, 67, 69, 74 and 78-79 are rejected under 35 U.S.C. 101(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996, as applied to claims 31-32, 34 and 84 above, and further in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.

Jackson et al. is applied as discussed for claims 31-32, 34 and 84 above, and teaches a method for application to the skin of a formulation comprising phytosphingosine. Jackson et al. further teaches that the composition can be used in the treatment of skin to reduce or delay the development of wrinkles associated with advancing age or with sun-induced aging (see column 2, lines 10-20, in particular.) Jackson et al. also teaches that further cosmetic adjuncts can be provided in the composition (see column 11, line 30 through column 1, line 15, in particular.)

Jackson et al. does not specifically teach providing a composition with a lipolytic agent as recited in claims 35, 40, 44, 67, 69 and 74-79.

Andre et al. teaches that an extract of *Tephrosia purpurea* provides powerful stimulation activity of the enzyme adenylate cyclase (lipolytic agent) (see column 1,

lines 30-45, in particular.) Andre et al. teaches that the extract can be provided in a cosmetic composition to provide anti-aging effects (see abstract, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extract of Andre et al. in the composition of Jackson et al, because Jackson et al. teaches applying a composition to reduce wrinkles associated with skin aging, and teaches the composition can have other adjuvants, and Andre et al. teaches that an extract that acts as an adenylate cyclase has anti-aging effects in cosmetic compositions. Thus, one of ordinary skill in the art would have been motivated to provide an adjuvant comprising the extract of Andre et al. in the wrinkle-treating composition of Jackson et al. and applying to skin, with the expectation of providing a composition that treats aging of skin such as wrinkles and has anti-aging effects. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.) Accordingly, the method of claim 35 is obvious over Jackson et al. and Andre et al.

Regarding the composition of claim 67, it is noted that Jackson et al. teaches a composition for reducing wrinkles associated with ageing, whereas Andre et al. teaches that a composition with an extract that is an adenylate cyclase enzyme stimulator



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(activating agent) can provide anti-aging effects, as discussed for claim 35. Jackson et al. also teaches that the composition can comprise a cosmetically acceptable vehicle (see column 5, lines 60-68, in particular), as recited in the claim. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the adenylate cyclase activating extract of Andre et al. in the wrinkle-treating composition of Jackson et al., with the expectation of providing a composition that treats aging of skin such as skin wrinkles and has anti-aging effects. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.) Accordingly, the composition of claim 67 is also obvious over Jackson et al. and Andre et al.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.) Thus the intended use recited in claim

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67, namely that the cosmetic composition is "notably intended for reducing subcutaneous excess fat," is not afforded patentable weight.

Regarding claims 40 and 74, Andre et al. teaches that the extract is an adenylate cyclase enzyme activator.

Regarding claim 69, Jackson et al. teaches a cosmetic composition comprising 0.1% phytosphingosine (see Example 1, in particular), and thus teaches providing the weight percentage recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phytosphingosine provided in the composition, according to the guidance provided by Jackson et al, to provide a composition having desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 44 and 78-79, Andre et al. teaches that the extract can be from *Tephrosia purpurea*, and also teaches that the extract can be provided in a topical composition in an amount between 0.01 to 5% by weight (see column 1, lines 45-55 and column 2, lines 20-25, in particular), which meets the range limitation recited in claims 44 and 79. Furthermore, it is considered that one of ordinary skill in the art at the time

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the invention was made would have found it obvious to vary and/or optimize the amount of extract provided in the composition, according to the guidance provided by Andre et al, to provide a composition having desired treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

### ***Conclusion***

No claims are allowed.

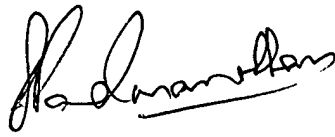
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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